UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION
PREVENTION

MEMORANDUM

DATE: August 23, 2011

SUBJECT: Efficacy Review for Accel Concentrate Disinfectant Cleaner;
EPA Reg. No, 74559-4;
DP Barcode: D390699

FROM: Michele E. Wingfield
Senior Science Advisor
Antimicrobials Division (7510P)

THRU: Dr. Tajah Blackburn, Team Leader
Product Science Branch
Antimicrobials Division (7510P)

8/23/11

TO: Marshall Swindell, PM 33/Demson Fuller
Regulatory Management Branch I
Antimicrobials Division (7510P)

APPLICANT: Virox Technologies, Inc
2770 Coventry Road
Oakville, Ontario L6H 6R1

FORMULATION FROM LABEL:

Active Ingredient(s)	% by wt.
Hydrogen Peroxide	4.25%
Inert Ingredients	95.75%
Total	100.00%

I BACKGROUND

The product, Accel Concentrate Disinfectant Cleaner (EPA Reg. No. 74559-4), is a one-step disinfectant cleaner, deodorizer with virucidal and fungicidal label claims. This submission is to add new label claims for disinfection, viruses, fungi and a new claim as a non-food contact sanitizer. With the exception of a single study, submitted with the data package, the applicant intends to support the additional label claims by citing data from Johnson/Diversey Inc.'s formulation, Oxy-Team Disinfectant Cleaner (EPA Reg. No. 70627-58). The study was conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant to EPA (dated June 2, 2011), one study (MRID 484979-02), eleven cited studies, Statements of No Data Confidentiality Claims for the study, and the proposed label.

II USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces, in healthcare settings, office buildings, schools, colleges, day care centers, funeral homes, animal life sciences laboratories, hotels, motels, foodservice establishment and other industrial and commercial areas. It is designed to treat the following surfaces. Vinyl, painted surfaces, plastic glass, mirrors, glazed ceramic, toilets, floors, walls, ceilings, sinks, sink basins another hard, non-porous non-food contact surfaces.

As a disinfectant: When used as directed, this product is highly effective against a wide variety (broad spectrum) of pathogenic microorganisms (including bacteria, antibiotic resistant bacteria, viruses, fungi, mold and mildew). At a 1:16 dilution (8 oz. of product per gallon of water), in the presence of 200 ppm hard water, 5% serum load and a 5 minute contact time, unless otherwise noted.

As a fungicide: Use at 1:16 dilution (8 oz. per gallon of water), and in the presence of a 5% serum load and five minute contact time at 20°C (68°F).

To Sanitize Non-Food Contact Surfaces: Dilute 1.0 oz. of product per gallon of water (1:128). Pre-clean heavily soiled hard non-porous surfaces. Apply Use Solution until thoroughly wet. Let stand for 3 minutes. Wipe surfaces (and let air dry).
Not for use on food contact surfaces or on food preparation areas.
Note: Do not use on glassware, utensils or dishes.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments

The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old, against

Salmonella enterica (ATCC 10708; formerly *Salmonella choleraesuis*), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442).

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria)

Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using the AOAC Germicidal Spray Products as Disinfectants Method)

The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Germicidal Spray Products as Disinfectants Method contains procedures for testing fungicidal activity. Ten carriers on each of 2 product samples representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Note: As an interim policy, EPA is accepting studies with dried carrier counts that are at least 10^4 for *Trichophyton mentagrophytes*, *Aspergillus niger*, and *Candida albicans*. EPA recognizes laboratories are experiencing problems in maintaining dried carrier counts at the 10^6 level. This interim policy will be in effect until EPA determines that the laboratories are able to achieve consistent carrier counts at the 10^6 level.

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 484979-02 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Surfaces, Virus: Minute virus of mice" Product Identity: Accel Concentrate Lot # 8835 and Lot # 8836, by Mary J. Miller, M.T.. Study conducted at ATS Labs. Study completion date – March 10, 2011. Project Number: A10852

This study was conducted against Minute virus of mice (ATCC VR-1346, Strain Prototype (p) Two lots of the product (Lot #s 8835 and 8836) Accel Concentrate were tested against the Minute virus of mice under the following conditions. The product was diluted 8 oz. per gallon of 200 ppm AOAC Synthetic Hard Water. 5% fetal bovine serum was added as an organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For the product lots, a dried virus film was exposed to 2.00 mL of the use solution for 4.5 minutes at 20.0°C. Following exposure, the plate was scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed immediately through Sephadex columns. The filtrates were tittered by 10-fold serial dilution and assayed for infectivity or cytotoxicity. The A9 cell line, which exhibits CPE in the presence of Minute virus of mice, was used as the indicator cell line in the infectivity assays. Cells in multiwell culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions prepared from test and control groups. The input virus control was inoculated in duplicate. Uninfected indicator cell cultures (cell controls) were inoculated with test medium alone. The cultures were incubated at 36 - 38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for seven days for the presence or absence of CPE, cytotoxicity, and for viability.

Note: Protocol deviations/amendments reported in the study were reviewed.

CITED STUDIES:

The following MRID studies were submitted to support these additional microorganisms:

Disinfection and virucide

Extended Spectrum β-Lactamase *Escherichia coli*	MRID 481382-02
Carbapenem-resistant *Klebsiella pneumoniae*	MRID 481382-03
Adenovirus type 8	MRID 481382-04
Influenza A (H1N1) virus	MRID 481382-05
Rhinovirus type 37	MRID 481382-06

Reduce contact time (5 minutes from 10 minutes) for
Trichophyton mentagrophytes MRID 481382-07

New Non-Food Contact Sanitization Claims

Staphylococcus aureus	MRID 481382-08
Enterobacter aerogenes	MRID 481382-08
Escherichia coli with extended beta-lactamase resistance	MRID 481382-09
Vancomycin Resistant *Enterococcus faecalis*	MRID 481382-09
Listeria monocytogenes	MRID 481382-09
Pseudomonas aeruginosa	MRID 481382-09
Salmonella enterica	MRID 481382-09

New lengthened use-solution claim

Staphylococcus aureus	MRID481382-10
Salmonella enterica	MRID481382-11
Pseudomonas aeruginosa	MRID481382-12

V RESULTS

MRID Number	Organism	Results		Dried Virus Count
			Lot Nos. 8835 & 8836	
484979-02	Minute virus of mice	10^{-1} to 10^{-7} dilutions	Cytotoxicity	$\geq 10^{5.25}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{1.5}$	

VI CONCLUSIONS

A. Conclusions Regarding Use of the Product as a Disinfectant

1. The cited efficacy data support the use of the product, Accel Concentrate Disinfectant Cleaner, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces at a 1:16 dilution in 200 ppm hard water and in the presence of a 5% organic soil load for a 5-minute contact time:

Extended Spectrum β-Lactamase *Escherichia coli*	MRID 481382-02
Carbapenem-resistant *Klebsiella pneumoniae*	MRID 481382-03
Adenovirus type 8	MRID 481382-04
Influenza A (H1N1) virus	MRID 481382-05
Rhinovirus type 37	MRID 481382-06

The data was reviewed and found to be acceptable for the cited product, 70657-58, on October 20, 2010 (for DP380693). Note: The registrant's representative's letter failed to include Carbapenem-resistant *Klebsiella pneumoniae;* however the proposed label included the referenced bacterium.

2. The cited efficacy data support the use of the product, Accel Concentrate Disinfectant Cleaner, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces at a 1:16 dilution in 200 ppm hard water and in the presence of a 5% organic soil load for a 5-minute contact time:

Adenovirus type 8	MRID 481382-04
Influenza A (H1N1) virus	MRID 481382-05
Rhinovirus type 37	MRID 481382-06

The data was reviewed and found to be acceptable for the cited product, 70657-58, on October 20, 2010 (for DP380693).

3. The cited efficacy data support the use of the product, Accel Concentrate Disinfectant Cleaner, as a disinfectant with fungicidal activity against *Trichophyton mentagrophytes* at a reduced contact time of 5 minutes. The cited MRID 481382-07 and accepted review of October 20, 2010 support this claim (for DP380693).

4. The cited efficacy data support the use of the product Accel Concentrate Disinfectant Cleaner as a non-food contact sanitizer against the following microorganisms:

Staphylococcus aureus	MRID 481382-08
Enterobacter aerogenes	MRID 481382-08
Escherichia coli with extended beta-lactamase resistance	MRID 481382-09
Vancomycin Resistant *Enterococcus faecalis*	MRID 481382-09
Listeria monocytogenes	MRID 481382-09
Pseudomonas aeruginosa	MRID 481382-09
Salmonella enterica	MRID 481382-09

The cited studies were reviewed and accepted on October 20, 2010 (for DP380693).

4. The cited studies, MRID Nos. 481382-10-12 support the use of the product Accel Concentrate Disinfectant Cleaner at an extended use-solution length against *Staphylococcus aureus*, *Salmonella enterica*, and *Pseudomonas aeruginosa* at a 1:16 dilution rate for 10 – 90 days.

5. The submitted efficacy data (MRID No. 484979-02) support the use of the product, Accel Concentrate Disinfectant Cleaner as a virucide against Minute virus of mice when tested at a 1:16 dilution in 200 ppm hard water, and in the presence of 5% soil load for a contact time of 4.5 minutes.

VII RECOMMENDATIONS

1. The proposed label claims that a 1:16 use solution of the product, Accel Concentrate Disinfectant Cleaner, is an effective disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of 200 ppm hard water and 5% serum for a 5-minute contact time:

Extended Spectrum β-Lactamase Resistance *Escherichia coli*
Carbapenem-resistant *Klebsiella pneumoniae*
Trichophyton mentagrophytes

These claims **are acceptable** as they are supported by the cited data.

2. The proposed label claims that a 1:16 use solution of the product, Accel Concentrate Disinfectant Cleaner, is an effective disinfectant against Minute virus of mice on hard, non-porous surfaces in the presence of 200 ppm hard water and 5% serum for 5 minute contact times. These claims **are acceptable** as they are supported by the cited data; however claims for acceptability at concentrations greater that 1:16 are unacceptable.

3. The proposed label claims that a 1:16-1:64 use solution of the product, Accel Concentrate Disinfectant Cleaner, is an effective disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of 200 ppm hard water and 5% serum for the contact times listed:

Adenovirus type 8	5 minutes
Influenza A (H1N1) virus	1 minute
Rhinovirus type 37	5 minutes

These claims **are acceptable** as they are supported by the cited data

4. The proposed label claims that a 10-90 day old aged 1:16 use solution of the product, Accel Concentrate Disinfectant Cleaner, is an effective disinfectant against *Staphylococcus aureus*, *Salmonella enterica*, and *Pseudomonas aeruginosa* on hard, non-porous surfaces in the presence of 200 ppm hard water and 5% serum for a 5-minute contact time. This claim **is acceptable** as it is supported by the cited data.

5. The proposed label claims that a 1:16 use solution of the product, Accel Concentrate Disinfectant Cleaner, is an effective sanitizer against the following microorganisms on hard, non-porous, non-food contact surfaces in the presence of 200 ppm hard water and 5% serum for a 30-second contact time:

Staphylococcus aureus
Enterobacter aerogenes
Escherichia coli with extended beta-lactamase resistance
Vancomycin Resistant *Enterococcus faecalis*
Listeria monocytogenes
Pseudomonas aeruginosa
Salmonella enterica

These claims **are acceptable** as they are supported by the cited data.

6. On page 4 of the proposed label, change "monocytogenese" to "monocytogenes".